(2)

No. 90-1245

FILED
MAR 5 1991
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1990

ANNE ELISABETH KOLLER,
Petitioner,

v.

RICHARDSON-MERRELL INC.,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

---

RESPONDENT'S BRIEF IN OPPOSITION

WALTER A. SMITH, JR.*
STEPHEN G. VASKOV
WILLIAM P. FLANAGAN
HOGAN & HARTSON
Columbia Square
555 13th Street, N.W.
Washington, D.C. 20004-1109
(202) 637-5728
Attorneys for Respondent Merrell Dow Pharmaceuticals Inc.

* Counsel of Record

WILSON - EPES PRINTING CO., INC. - 789-0096 - WASHINGTON, D.C. 20001

QUESTION PRESENTED

Should this Court now grant certiorari to determine the particular quantum of evidence required to sustain a jury verdict that the drug Bendectin causes human birth defects, when the Court has already denied certiorari on that issue three times in the last two Terms and when the Courts of Appeals are unanimous that the body of evidence presented in this case is insufficient to sustain such a verdict?

CORPORATE AFFILIATIONS OF RESPONDENT

Respondent Merrell Dow Pharmaceuticals Inc., sued herein under its predecessor name Richardson-Merrell Inc., is a wholly owned subsidiary of Marion Merrell Dow Inc., which is approximately ⅔ owned by The Dow Chemical Company. Their subsidiaries and affiliates that have securities in the hands of the public are the following:

Arabian Chemical Company Limited;
Compagnie des Services Dowell Schlumberger;
DCU/LB TRUST;
Alamo Land Company Inc.;
Dexco Polymers;
Donichem Chemical KFT;
Transformadora de Etileno S.A.;
Chimtrade;
Vorakim Kimya Sanayi Ve Ticaret A.S.;
Dowell Schlumberger Canada Incorporated;
Fort Saskatchewan Ethylene Storage Limited Partnership;
H-D Tech Inc.;
Wabiskaw Explorations Ltd.;
Cromarty Petroleum Company Limited;
Petroquimica-Dow S.A.;
Ulsan Pacific Chemical Corporation;
Dow Corning Corporation;
Epoxital;
First Chemical Factoring S.p.A.;
Oronzio de Nora Technologies S.p.A.;
Dow Kakoh Kabushiki Kaisha;
Dow Mitsubishi Kasei Limited;
Anticorrosives Industriales Ltda.;
Family Com. e Ind. de Produtos de Limpeza Ltda.;
Dow-United Technologies Composite Products Inc.;
Dowell Schlumberger Corporation;
Dowell Schlumberger Inc.;
El Dorado Terminals Company;

Gurit-Essex, A.G.;
Etoxilados Del Plata S.A.;
Joliet Marine Terminal Trust Estate;
Marion Merrell Dow Inc.;
Gruppo Lepetit S.p.A.;
Merrell Dow Funai K.K.;
MDP (Holdings) Ltd.;
Nordic Laboratories Inc.;
Tanabe-Marion Laboratories;
Fort Saskatchewan Ethylene Storage Corporation;
Pacific Indomas Plastic Indonesia;
Pacific Plastics (Thailand) Limited;
Promix System;
Airco Generon Systems;
DowElanco;
Eurosemances, S.A.;
DowElanco B.V.:
P.T. Pacific Chemicals Indonesia;
Pacific Chemicals Berhad;
Generon Systems;
Generon Systems AG;
Scotdril Offshore Company;
The Cynara Company;
Dow Chemical Iberica S.A.;
Lucky Dow Chemical Ltd.;
SD Group Service Company Ltd.;
Siam Strene Monomer Ltd.;
Siam Synthetic Latex Company;
DH Compounding Company;
Elanco Ihara K.K.;
Zhejiang Pacific Chemical Corporation.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
CORPORATE AFFILIATIONS OF RESPONDENT	ii
TABLE OF AUTHORITIES	vi
INTRODUCTION	1
COUNTERSTATEMENT OF THE CASE	2
A. The Record Concerning Bendectin	3
B. The Unanimous Courts of Appeals' Decisions Concerning Bendectin	5
C. The Opinions Below	9
REASONS FOR DENYING THE WRIT	9
1. The Questions Raised by Petitioner Are Not Presented by This Case	10
2. The Judgment in This Case Is of Very Limited Application	15
3. This Case Presents No Circuit Conflict Meriting This Court's Attention	17
CONCLUSION	19

TABLE OF AUTHORITIES

CASES: Page

Anderson v. *Liberty Lobby, Inc.*, 477 U.S. 242 (1986) 12
Brock v. *Merrell Dow Pharmaceuticals Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166, *reh'g denied en banc*, 884 F.2d 167 (5th Cir. 1989), *cert. denied*, 110 S. Ct. 1511 (1990) ..... *passim*
Celotex Corp. v. *Catrett*, 477 U.S. 317 (1986) 11
Christophersen v. *Allied-Signal Corp.*, 902 F.2d 362, *reh'g granted en banc*, 914 F.2d 66 (5th Cir. 1990) 16
DeLuca v. *Merrell Dow Pharmaceuticals Inc.*, 911 F.2d 941 (3d Cir. 1990) ..... *passim*
Ealy v. *Richardson-Merrell Inc.*, 897 F.2d 1159 (D.C. Cir.), *cert. denied*, 111 S. Ct. 370 (1990) .. *passim*
Ferebee v. *Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984) .. 16
In re Richardson-Merrell Inc. "Bendectin" Products Liability Litigation, 624 F. Supp. 1212 (S.D. Ohio 1985), *aff'd in part, vacated in part, rev'd in part*, 857 F.2d 290 (6th Cir. 1988), *cert. denied*, 488 U.S. 1006 (1989) 5
Lynch v. *Merrell-National Laboratories*, 646 F. Supp. 856 (D. Mass. 1986), *aff'd*, 830 F.2d 1190 (1st Cir. 1987) ..... *passim*
Matsushita Electrical Industrial Corp. v. *Zenith Radio Corp.*, 475 U.S. 574 (1986) 13
Peteet v. *Dow Chemical Co.*, 868 F.2d 1428 (5th Cir.), *cert. denied*, 110 S. Ct. 328 (1989) 18
Richardson v. *Richardson-Merrell Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S. Ct. 218 (1989) ..... *passim*
Shatkin v. *McDonnell Douglas Corp.*, 727 F.2d 202 (2d Cir. 1984) 18
United States v. *Johnston*, 268 U.S. 220 (1925) 14
Viterbo v. *Dow Chemical Co.*, 826 F.2d 420 (5th Cir. 1987) 18
Washington v. *Armstrong World Industries, Inc.*, 839 F.2d 1121 (5th Cir. 1988) 18

TABLE OF AUTHORITIES—Continued

Page

Wilson v. *Merrell Dow Pharmaceuticals Inc.*, 893 F.2d 1149 (10th Cir. 1990) 4, 6, 18

RULES:

Fed. R. Civ. P. 56 ..... 10, 12, 17
Fed. R. Evid. 402 18
Fed. R. Evid. 403 18
Fed. R. Evid. 702 18
Fed. R. Evid. 703 ..... *passim*

OTHER AUTHORITIES:

T. Stedman, *Stedman's Medical Dictionary* (25th ed. 1990) 3

IN THE

Supreme Court of the United States

OCTOBER TERM, 1990

No. 90-1245

ANNE ELISABETH KOLLER,
Petitioner,

v.

RICHARDSON-MERRELL INC.,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

---

RESPONDENT'S BRIEF IN OPPOSITION

INTRODUCTION

This petition represents the fourth time in the last two years that this Court has been asked to grant certiorari to determine the quantum of evidence required to sustain a jury verdict that the drug Bendectin causes human birth defects. The Court denied certiorari on the issue twice in the 1989 Term [1] and a third time in the 1990 Term.[2] This fourth petition repeats almost ver-

---

[1] *Richardson* v. *Richardson-Merrell Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S. Ct. 218 (1989); *Brock* v. *Merrell Dow Pharmaceuticals Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166, *reh'g denied en banc*, 884 F.2d 167 (5th Cir. 1989), *cert. denied*, 110 S. Ct. 1511 (1990).

[2] *Ealy* v. *Richardson-Merrell Inc.*, 897 F.2d 1159 (D.C. Cir.), *cert. denied*, 111 S. Ct. 370 (1990).

batim the same arguments made in the prior three petitions, *i.e.*, that there is a split in the circuit courts on the issue and that the grant of judgment against Bendectin plaintiffs unconstitutionally deprives them of their "day in court."

In fact, however, as was shown in Respondent Merrell Dow's previous oppositions[3] and is shown again here, rather than being split on the matter *all* circuits addressing the question have held that the quantum of evidence presented by Bendectin plaintiffs (and presented again in this case) is insufficient as a matter of law to sustain a jury verdict. And, far from raising a constitutional question, the circuits' decisions represent a routine exercise of the federal courts' responsibility under the Federal Rules of Evidence and Federal Rules of Civil Procedure to avoid duplicative, unnecessary trials where a party's case simply is insufficient to sustain a jury verdict.

At bottom, as was true in the previous three petitions, this case presents nothing more than a *factual* inquiry into the available evidence concerning Bendectin, an inquiry that has produced the circuits' *unanimous* view that that evidence does not reasonably support a determination that Bendectin causes human birth defects. There is nothing in this inquiry that merits this Court's attention. And there is nothing new on this inquiry in the present petition. It should be denied.

COUNTERSTATEMENT OF THE CASE

Petitioner's Statement of the Case is a highly inaccurate account both of the record evidence concerning Bendectin and the courts' analysis of that evidence.[4] Indeed, much of Petitioner's description of Bendectin consists of *completely undocumented* assertions that Bendectin

---

[3] Respondent Merrell Dow Pharmaceuticals Inc. ("Merrell Dow") was preceded in interest by Richardson-Merrell Inc.

[4] *See* Pet. 3-17. In this opposition we cite the petition as "Pet." and the separate appendix filed by Petitioner as "Pet. App.".

plaintiffs have made for years, but which the courts have consistently found those plaintiffs unable to establish. Accordingly, in this Counterstatement we describe (a) the documented record concerning Bendectin and (b) the courts' analysis of that record. We follow that with (c) an account of the opinions in this case.

A. The Record Concerning Bendectin

Bendectin is a prescription drug used primarily to treat nausea and vomiting in early pregnancy. Merrell Dow began marketing Bendectin in 1957, shortly after obtaining the approval of the FDA.[5] Thereafter, Bendectin became the leading treatment for women suffering from morning sickness—indeed, between 1957 and 1983 Bendectin was used in over thirty million pregnancies worldwide.[6]

After the thalidomide incident in the early 1960s, questions concerning the teratogenicity[7] of *any* drug or substance ingested during pregnancy arose. Accordingly, in 1963 Merrell Dow began conducting its own studies to determine whether or not Bendectin causes birth defects.[8] Likewise, in the nearly thirty years since then independent researchers throughout the world conducted and published epidemiological studies concerning Bendectin.[9] Significantly, not a single one of those studies concluded that there is a statistically significant association or causal connection between Bendectin and birth defects.[10]

---

[5] *See Richardson*, 857 F.2d at 824.

[6] *See id.*

[7] A teratogen is a substance or agent capable of causing abnormal development in humans. *See* T. Stedman, *Stedman's Medical Dictionary* 1563 (25th ed. 1990).

[8] *See Lynch* v. *Merrell-National Laboratories*, 830 F.2d 1190, 1193 (1st Cir. 1987).

[9] *See id.* at 1193-94.

[10] *See id.* at 1194; *Ealy*, 897 F.2d at 1162.

Moreover, in 1980 the FDA's Fertility and Maternal Health Drugs Advisory Committee, after studying the relevant literature and conducting a full hearing on the issue, concluded that "there was no increased incidence of birth defects among Bendectin-exposed infants; that there was no need for further animal or epidemiological studies; and that Bendectin should not be withdrawn from the market." [11] The FDA adopted the Committee's findings, and to this day continues its approval of Bendectin.[12]

Nevertheless, in 1983 Merrell Dow voluntariiy ceased the production and sale of Bendectin as a result of the large costs of litigation concerning the drug.[13] Significantly, after production ceased and notwithstanding Bendectin's prior wide use, there was *no* decrease in the overall incidence of birth defects.[14] Furthermore, even after production ceased, studies of the drug continued to be published concerning its use so that there are to date almost forty published epidemiological studies on the subject.[15] And, most significant of all, from this "wealth of published epidemiological data [that] has been amassed, none * * * has concluded that [Bendectin] is teratogenic." [16] Consequently, there now exists a "nearly uni-

---

[11] *Richardson*, 857 F.2d at 827. Petitioner's completely unsupported assertions that the FDA advisory committee was "convened largely at the behest of Merrell [Dow]" and that Merrell Dow thereby "garnered some governmental support" for Bendectin (Pet. 9) are disingenuous in the extreme. There is no evidence whatever in this record or that of any other Bendectin case that even suggests that Merrell Dow exerted any type of improper influence or control over the advisory committee or its conclusions.

[12] *See Richardson*, 857 F.2d at 824.

[13] *See id.*

[14] *See Lynch*, 830 F.2d at 1194.

[15] *Wilson* v. *Merrell Dow Pharmaceuticals Inc.*, 893 F.2d 1149, 1154 (10th Cir. 1990).

[16] *Richardson*, 857 F.2d at 832.

versal scientific consensus" that Bendectin does not cause birth defects.[17]

B. The Unanimous Courts of Appeals' Decisions Concerning Bendectin

In the early 1980s, while the scientific consensus on Bendectin was being formed, judicial dockets throughout the country swelled with Bendectin cases.[18] Most of these cases were resolved in 1985 in a single multidistrict consolidated trial[19] involving more than 1,100 Bendectin plaintiffs.[20] The first—and ultimately dispositive—issue tried and presented to the jury in that case was whether Bendectin in fact causes birth defects.[21] In March 1985 the jury determined that Bendectin does not cause birth defects, and judgment was accordingly entered in Merrell Dow's favor against all plaintiffs who were involved in the consolidated trial.[22] Thereafter, the Sixth Circuit affirmed the jury's verdict,[23] and this Court thereafter denied plaintiffs' petition for certiorari.[24]

Since the multidistrict verdict, unanimous consensus concerning Bendectin has developed in the federal appellate courts, *i.e.*, the courts that have fully addressed the question all have concluded that the current body of scientific evidence is, as a matter of law, an insufficient

---

[17] *Id.* at 827.

[18] *See DeLuca* v. *Merrell Dow Pharmaceuticals Inc.*, 911 F.2d 941, 949 (3d Cir. 1990).

[19] *In re Richardson-Merrell Inc. "Bendectin" Prods. Liab. Lit.*, 624 F. Supp. 1212 (S.D. Ohio 1985).

[20] *See In re Bendectin Lit.*, 857 F.2d 290, 294-95 (6th Cir. 1988), *cert. denied*, 488 U.S. 1006 (1989).

[21] *Id.* at 296.

[22] *Id.*

[23] *Id.* at 32[illegible].

[24] 488 U.S. 1006 (1989).

basis upon which a reasonable jury could find that Bendectin causes birth defects.[25] And, as noted, this Court has three times denied certiorari to review those decisions. As a result, there are but a handful of Bendectin cases still pending.[26]

Thus, following the multidistrict verdict, the First Circuit, on appeal of an order entering summary judgment in Merrell Dow's favor, examined the legal sufficiency of the scientific evidence to support a claim that Bendectin causes birth defects.[27] Upon reviewing the records of testimony in other Bendectin trials, the expert depositions and affidavits on file, and the scientific studies since 1963, that court concluded that even when viewing the evidence in the light most favorable to plaintiffs, there was still insufficient evidence upon which plaintiffs could carry their burden of proof.[28]

Thereafter, the District of Columbia Circuit examined the legal sufficiency of the scientific evidence on Bendectin on review of a trial court's decision to enter judgment for Merrell Dow notwithstanding a contrary verdict by the jury.[29] The specific question before the D.C. Circuit in *Richardson* was "not whether there was *some evidence*, but whether * * * there was *sufficient evidence* upon which a jury could properly base a verdict for the [plaintiffs]."[30] In resolving that question, the D.C. Circuit

---

[25] *Lynch*, 830 F.2d at 1197; *Richardson*, 857 F.2d at 833; *Brock*, 874 F.2d at 315; *Ealy*, 897 F.2d at 1164; *see also DeLuca*, 911 F.2d at 958 (noting that issue of whether Bendectin is a teratogen may be "susceptible of resolution by summary judgment"); *Wilson*, 893 F.2d at 1155 (affirming verdict in favor of Merrell Dow, and noting that scientific evidence of record was "perhaps even enough to sustain a directed verdict").

[26] *See DeLuca*, 911 F.2d at 943.

[27] *Lynch*, 830 F.2d at 1193-97.

[28] *Id.* at 1193-94, 1197.

[29] *Richardson*, 857 F.2d at 825.

[30] *Id.* at 828 (emphasis in original).

found that based on the wealth of published, peer-reviewed epidemiological data that has been amassed demonstrating that Bendectin does not cause birth defects, the four factors that formed the bases for the contrary opinions of plaintiffs' causation experts—chemical structure activity; *in vitro* studies; *in vivo* animal studies; and unpublished, non-peer-reviewed recalculations of epidemiological studies—failed to provide an adequate foundation to support a conclusion that Bendectin in fact causes birth defects.[31]

The *Richardson* Court based its reasoning on its finding that with respect to Bendectin, the causation issue does not "stand[] at the frontier of current medical and epidemiological inquiry," but is instead "at the other end of the spectrum, a great distance from the 'frontier * * *.'"[32] As a result, "the law now has the benefit of twenty years of scientific study, and the published results must be given their just due."[33] The Court therefore concluded that as a matter of law none of the described types of evidence presented by plaintiffs' experts could provide sufficient evidence upon which a jury could reasonably find that Bendectin causes birth defects.[34] The plaintiffs in *Richardson* thereafter petitioned this Court for a writ of certiorari, but that petition was denied.[35]

---

[31] *Id.* at 829-31. Specifically, regarding the first three types of causation evidence—chemical, *in vitro* and *in vivo* studies—the Court stated that "[s]tudies of this kind, singly or in combination, are not capable of proving causation in human beings in the face of an overwhelming body of contradictory epidemiological evidence." *Id.* at 830. The Court found that the fourth kind of evidence—non-peer-reviewed recalculations of published epidemiological studies—is simply insufficient to refute the "wealth of published epidemiological data [that] has been amassed, none of which has concluded" that Bendectin causes birth defects. *Id.* at 831-32.

[32] *Id.* at 832 (citation omitted).

[33] *Id.*

[34] *Id.* at 828, 833.

[35] 110 S. Ct. 218 (1989).

Following *Richardson*, the Fifth Circuit reversed a trial court's entry of judgment on a jury verdict for the plaintiffs in a Bendectin case.[36] In doing so, the Court in *Brock* specifically concluded that the scientific evidence adduced at trial by plaintiffs was insufficient evidence upon which a jury could make a reasonable inference on causation.[37] After the denial of a petition for rehearing and a suggestion for rehearing en banc in *Brock*, this Court denied the plaintiffs' petition for certiorari.[38]

After the Fifth Circuit's decision in *Brock*, the D.C. Circuit again examined the sufficiency of plaintiffs' expert causation testimony in light of "the existing body of published epidemiological studies, all finding no significant statistical association between ingestion of Bendectin and birth defects." [39] In *Ealy*, the Court confirmed "the binding legal precedent" established by the D.C. Circuit in *Richardson*.[40] Finding no material difference in the scientific evidence in the two cases, the Court in *Ealy*, like the Court in *Richardson*, found that the evidence was "so one-sided that no reasonable juror could find on the admissible evidence that Bendectin caused the plaintiff's birth defects." [41] The plaintiffs in *Ealy* also petitioned for certiorari, and that petition as well was denied.[42]

It is against this background, particularly the *Richardson* and *Ealy* decisions, that the Court of Appeals based its summary affirmance of the judgment entered in Merrell Dow's favor in this case.

---

[36] *Brock*, 874 F.2d at 315.

[37] *Id.*

[38] 110 S. Ct. 1511 (1990).

[39] *Ealy*, 897 F.2d at 1161, 1164.

[40] *Id.* at 1162.

[41] *Id.* at 1161.

[42] 111 S. Ct. 370 (1990).

C. The Opinions Below

Before trial, the District Court stayed this case pending resolution of the appeal in *Richardson*. Once that appeal was decided, the District Court lifted the stay and issued a show cause order directing plaintiff to "identify specific, admissible, expert evidence of a causal relationship between Bendectin and limb defects which would meet the standards announced in the *Richardson* decision." Pet. App. A4. Thereafter, the District Court reviewed plaintiff's response to the show cause order and found that plaintiff had failed to demonstrate that she would rely on scientific evidence other than that which the D.C. Circuit had rejected as a matter of law in *Richardson*. *Id.* at A8. Consequently, the District Court determined that plaintiff failed to present sufficient evidence upon which a jury could find in her favor on the question of causation. *See id.* at A8-9. The District Court accordingly concluded that Merrell Dow was entitled to judgment as a matter of law.

Plaintiff's appeal of that judgment was stayed pending the decision in *Ealy*. After the *Ealy* Court confirmed the rule of law announced in *Richardson*, the Court of Appeals below—in a *per curiam* Order—summarily affirmed the judgment "substantially for the reasons stated by the district court" in its opinion. *Id.* at A1. Citing *Richardson* and *Ealy*, the Court below noted that summary affirmance was appropriate because the "merits of the parties' positions are so clear." *Id.* at A2.

REASONS FOR DENYING THE WRIT

The entire premise of this petition is the contention that the D.C. Circuit has employed Federal Rule of Evidence 703 in this case as a predicate for claiming broad, far-reaching, unprecedented federal-court powers, in contradiction of other circuit court constructions of Rule 703 and in violation of Petitioner's constitutional rights. None of this is correct. Rather, as we will show, the

judgment in this case is not premised on Rule 703 at all, and the questions raised by Petitioner are simply not presented by this case. Moreover, the judgment entered in this case is of very limited application. Finally, the judgment is in complete accord not only with settled principles established by this Court, but also with all other circuit court decisions addressing similar circumstances. For all these reasons, the writ should be denied.

1. The Questions Raised by Petitioner Are Not Presented by This Case

Petitioner asks the Court to review three questions: (1) whether federal courts may exclude expert testimony under Federal Rule of Evidence 703 on the ground that the testimony is "incorrect and hence not 'reasonable' "; (2) whether federal courts may use the Federal Rules of Evidence to establish "particular conclusions about ultimate scientific facts"; and (3) whether federal courts may constitutionally "pronounce binding conclusions of ultimate scientific fact" that preclude all subsequent parties from challenging those pronouncements. The most important reason for denying the writ is that *none* of these questions is presented by this case because neither of the lower courts held anything remotely resembling the propositions contained in the questions.

In formulating her questions, Petitioner has simply ignored the procedural posture in which the lower courts ruled in this case and the content of their rulings. As noted, the District Court granted summary judgment in Merrell Dow's favor in this case and the Court of Appeals summarily affirmed that judgment. That judgment was issued under Federal Rule of Civil Procedure 56, not Federal Rule of Evidence 703. Indeed, Rule 703 is *not even mentioned* in *either* lower court opinion, much less used as the predicate for the propositions of law framed by Petitioner.

Moreover, far from being based on a binding *unchallengable* pronouncement of scientific fact by the lower

courts, summary judgment was granted on the following unremarkable analysis: in a *prior*, factually similar case (*Richardson*), the evidence adduced was found insufficient as a matter of law to persuade a reasonable jury that Bendectin causes birth defects given the overwhelming evidence adduced to the contrary in that case. In *this* case, the same overwhelming contrary evidence was adduced by Merrell Dow; accordingly, in *this* case Petitioner was expressly invited by a show cause order to present evidence *other* than that found insufficient in *Richardson*. Pet. App. A4. As the District Court stated: "the law of this Circuit is that announced in *Richardson*: the issue of causation shall not be presented to a jury unless the plaintiffs offer scientific evidence other than that which has heretofore been proffered." *Id.* at A8-A9.

Because Petitioner declined or was unable to present any further evidence on the issue, the District Court not surprisingly granted summary judgment, holding that Petitioner had "failed to meet [her] burden of proving causation such that the issue may be presented to a trier of fact." *Id.* at A9. The Court of Appeals thereafter summarily affirmed "substantially for the reasons stated by the District Court * * *." *Id.* at A1.

Thus, the judgment now before this Court is simply not premised on Rule 703 at all, let alone upon the interpretation of that Rule suggested by Petitioner.[43] Rather, it is premised on the standard, obligatory responsibility of the federal courts to ensure that a plaintiff is prepared to adduce evidence sufficient to meet its burden of proof on every element of its claim before permitting a trial. As this Court held in *Celotex Corp.* v. *Catrett*, 477 U.S. 317, 327 (1986), "[t]he Federal Rules of Civil Procedure have for almost 50 years authorized" entry of summary judgment "upon proper showings of the lack of

---

[43] We show below that even if the case were deemed to be premised in part on Rule 703, that Rule was correctly applied and the application was not in conflict with the other circuit courts.

a genuine, triable issue * * *." Such entry of judgment is "not * * * a disfavored procedural shortcut," but a means to prevent "factually insufficient claims * * * from going to trial with the attendant unwanted consumption of public and private resources." And such judgment is not merely appropriate, but is "mandate[d]" by the "plain language of Rule 56(c) * * * against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case * * *." *Id.* at 322.

Here, because the evidence Petitioner was prepared to produce was factually insufficient to persuade a reasonable jury on a key element of her case—causation—the District Court directed her to produce further evidence in order to withstand summary judgment. Because Petitioner could produce nothing more, the standard of proof unanimously agreed to by the circuits in *Brock*, *Lynch*, and *Richardson* precluded her from proceeding and avoided the need for a trial.

That outcome is a straightforward application of summary judgment procedure. It is not, as Petitioner would have it, an example of federal courts determining which "scientific truths" are correct and which are not. As this Court held in *Anderson* v. *Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986), at the summary judgment stage the federal courts do not "determine the truth of the matter but * * * whether there is a genuine issue for trial." However, the Court held, there is *no* such "genuine issue" where the party with the burden of proof presents evidence that "is merely colorable" or is "not significantly probative." *Id.* at 249-50. And, where the evidence is "so one-sided" that no reasonable jury could reject it, a case is ripe for decision "as a matter of law." *Id.* at 251-52. *That* is the basis upon which this case was decided.

Petitioner's insistence that something more is involved —that the judgment in this case constitutes an improper,

specialized pronouncement of ultimate scientific fact—is simply not so. Of course, *any* time a court deems evidence insufficient to demonstrate a key fact at issue it has necessarily made a judgment that for burden-of-proof purposes the fact has not been adequately established. But such a determination is not based on a special pronouncement or inappropriate claim of judicial expertise; rather, it is based simply on the failure of the party with the burden of proof to produce enough evidence to persuade a reasonable jury that the asserted fact is so. These simple, basic principles were applied to Bendectin in this case and there is nothing special about their application.[44]

Finally, the proposition that this case presents the specter of the courts unconstitutionally announcing scientific truth by fiat and improperly barring later parties from ever challenging that "truth" is pure fantasy. Again, the only thing the courts in this case determined, based on settled summary judgment procedures and fundamental principles of *stare decisis*, was that a certain quantum of evidence had been found insufficient as a matter of law to raise a "genuine issue" on causation in a tort case. Accordingly, Petitioner was given full and fair opportunity to demonstrate whether she could adduce evidence to exceed the level found insufficient to meet the burden of proof under the governing standard. Because she could not do so, summary judgment was of course entered against her—not because of any unconstitutional treatment of Petitioner, and certainly not because she

---

[44] Obviously, these principles do not give way in the face of expert testimony; federal judges must still ensure that such testimony is sufficient to sustain a reasonable jury's verdict. *See, e.g., Matsushita Elec. Indus. Co.* v. *Zenth Radio Corp.*, 475 U.S. 574, 585-87, 593 (1986) (even in case involving highly complex antitrust economic analysis, party still must show "genuine" issue of fact to survive summary judgment, and where "factual context renders [a party's] claim implausible," summary judgment should be granted).

was denied her "day in court," but through a routine application of standard principles.[45]

In the final analysis, the only thing remarkable about this petition is the rule of law Petitioner would have this Court consider. Her view apparently is that there can be *no* standards governing the quantum of evidence in cases involving experts; rather, every plaintiff must be permitted to go to trial with any claim that any expert will support, no matter how many times that precise claim has previously been tried and found wanting, and no matter how many courts have found the claim so unreasonable that no jury could sustain it. Petitioner's view of course has no support whatever in the law and certainly does not merit the attention of this Court on certiorari.

In summary, despite Petitioner's efforts to create issues of importance warranting the Court's review, the questions she frames are simply not presented by this case. Ultimately, this case concerns only a factual inquiry about Bendectin's use and effects. Such an inquiry is not the role of this Court. "We do not grant certiorari to review evidence and to discuss specific facts." *United States* v. *Johnston*, 268 U.S. 220, 227 (1925). Certiorari should be denied.

---

[45] Moreover, the circuit courts have certainly not foreclosed later Bendectin plaintiffs from adducing new evidence on the causation issue. To the contrary, as the D.C. Circuit—and others—have recognized, it is only the *current* state of scientific proof that will prove fatal to plaintiffs' cases. "It may well be that future scientific research will generate new * * * data providing an adequate basis for an expert's opinion that Bendectin is a human teratogen * * * Until that day, the existing body of epidemiological studies * * * must be recognized as the measuring stick for the admissibility of expert testimony on this issue." *Ealy*, 897 F.2d at 1163-64; *see also Brock*, 874 F.2d at 315 ("* * * we do not wish this case to stand as a bar to future Bendectin cases in the event that new and conclusive studies emerge which would give a jury a firmer basis on which to determine the issue of causation").

2. The Judgment in This Case Is of Very Limited Application

Although Petitioner asserts that the judgment in this case has far-reaching application, by the clear terms of the summary lower-court opinions the judgment is narrow and is applicable only to cases involving Bendectin. Furthermore, in light of the unanimity of the circuit courts regarding the sufficiency standard applicable to Bendectin cases and this Court's three denials of certiorari to review that standard, the vast bulk of the Bendectin cases are now final. Accordingly, a grant of certiorari in this case would affect very few cases.

Petitioner's arguments to the contrary again ignore what the Court of Appeals below actually did—apply its assessment of the causation evidence affecting Bendectin, as previously announced by that Court in *Richardson* and confirmed in *Ealy*, to the nearly identical evidence offered on that same issue in this case. In fact, because of the precedential force of *Richardson* and *Ealy*, there is no substantive Court of Appeals opinion for this Court to review on certiorari at all, but only a summary affirmance of the District Court's judgment. For this reason, Petitioner's argument is really not an attack on any reasoning of the Court of Appeals in this case, but yet another attack on the reasoning of the D.C. Circuit's earlier decisions in *Richardson* and *Ealy*, which this Court has already declined to review.

Moreover, even if the Court were willing to revisit *Richardson* and *Ealy* in this case, those decisions are themselves quite narrow. As the D.C. Circuit explicitly recognized in *Richardson*, Bendectin presents a "unique" situation in tort litigation, one in which "a wealth of published epidemiological data has been amassed [over twenty years]," and "*none* of [it] has concluded that the drug is teratogenic." 857 F.2d at 832 (emphasis sup-

plied). In those "unique" circumstances, the Court held, the causation question is not at the "frontier of current medical and epidemiological inquiry" where the status of scientific knowledge could reasonably lead experts and juries to different conclusions. *Id.* (citing *Ferebee* v. *Chevron Chemical Co.*, 736 F.2d 1529, 1534 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984)). Rather, the Bendectin inquiry is "at the other end of the spectrum," —where "the body of *published* epidemiological opinions on the subject is extensive, indeed massive, and all such opinions point to the same conclusion." *Richardson*, 857 F.2d at 832; *Ealy*, 897 F.2d at 1162 (emphasis in original). Where that is so—and *only* where that is so—the D.C. Circuit has concluded, as have the other circuits,[46] that reasonable juries could not reject such overwhelming evidence. There is absolutely nothing in any of the circuit courts' opinions suggesting that their treatment of Bendectin would authorize entry of judgment in cases where reasonable juries *could* differ.[47]

Furthermore, not only is the judgment in this case a narrow one—indeed, a "unique" one—the number of cases to which it could yet be applied is quite small. Indeed, as previously discussed, in the wake of the unanimous federal circuit decisions and this Court's three denials of certiorari, only a few Bendectin cases remain pending. Accordingly, any grant of certiorari to review the lower courts' treatment of the "unique" circumstances surrounding Bendectin would have severely limited application.

---

[46] *Lynch*, 830 F.2d at 1196-97; *Brock*, 874 F.2d at 315.

[47] *See, e.g., Christophersen* v. *Allied-Signal Corp.*, 902 F.2d 362, 367 (refusing to extend *Brock* to non-Bendectin cases), *reh'g granted en banc*, 914 F.2d 66 (5th Cir. 1990).

3. This Case Presents No Circuit Conflict Meriting This Court's Attention

Petitioner insists, nevertheless, that this case should be seen as presenting a "persistent and important conflict" in the circuit courts "over the construction of Rule 703." Pet. 3, 24, 25. But that is not so. Indeed, as already shown, this case does not present a conflict with respect to Rule 703 at all. Moreover, as also shown, even if this case were thought to rest in part on a D.C. Circuit interpretation of Rule 703, a review of that interpretation by this Court would affect very few cases. Indeed, it is highly unlikely that it would even affect the ultimate judgment in this very case; for even if Petitioner's expert testimony were deemed admissible under Rule 703, the lower court (following *Richardson* and *Ealy*) would still deem that evidence insufficient to support a jury verdict under Federal Rule of Civil Procedure 56. Accordingly, the judgment against Petitioner would in any case be affirmed.

Finally, and in any event, although Petitioner advances much conclusory language about a "clear, persistent and important" conflict in the circuit courts, she never shows that one actually exists. In fact, no significant difference of any kind exists among the circuit courts as to the role of federal courts in determining the admissibility of expert testimony. Rather, each circuit that Petitioner claims to be in conflict over the meaning of Rule 703 has ruled that federal trial courts are obliged, when ruling on a dispute about the admissibility of expert testimony, to conduct a case-by-case, factual inquiry into the sufficiency and foundation of that expert's testimony.[48] And each circuit court of appeals decision cited

---

[48] Although there may be minor differences in the precise formulation these courts apply in conducting their review of proffered expert testimony, Petitioner does not and cannot show any of these differences to be improper or to be sufficiently important to warrant this Court's review.

by Petitioner agrees that the question of the admissibility of an expert's testimony is a question of law to be decided by the trial court [49] based on the application and interplay of the several pertinent rules of evidence.[50]

This agreement among the circuit courts [51] includes the decision on which Petitioner most heavily relies, *DeLuca v. Merrell Dow Pharmaceuticals Inc.*, *supra*. Indeed, the Third Circuit in *DeLuca* and the D.C. Circuit in *Richardson* and *Ealy* agree that the admissibility of expert testimony is to be determined by the *court*, and that the *court* must make that determination after conducting a factual

---

[49] *See, e.g., Richardson*, 857 F.2d at 833; *Lynch* v. *Merrell-National Laboratories*, 646 F. Supp. 856, 865-66 (D. Mass. 1986), *aff'd*, 830 F.2d 1190 (1st Cir. 1987); *Washington* v. *Armstrong World Industries, Inc.*, 839 F.2d 1121, 1123 (5th Cir. 1988); *Peteet* v. *Dow Chemical Co.*, 868 F.2d 1428, 1432 (5th Cir.), *cert. denied*, 110 S. Ct. 328 (1989); *Wilson*, 893 F.2d at 1153.

[50] Among those rules are Rule 702 (authorizing admission of expert testimony where it will "assist the trier of fact"), Rule 703 (permitting expert testimony if it is reliable and has an adequate foundation), Rule 402 (permitting admission of evidence if it is relevant), and Rule 403 (permitting exclusion of relevant evidence if it can mislead or confuse the fact-finder).

[51] *See, e.g., Richardson*, 857 F.2d at 829 and n.39 (while Rule "703 lays the foundation for our consideration of what constitutes adequate expert testimony," other relevant rules are "702, which permits admission of expert testimony only if it will assist the trier of fact, and * * * 403, which allows the trial court to exclude testimony if it is misleading or confusing, or if its probative value is outweighed by considerations of prejudice, confusion, or waste of time"); *Shatkin* v. *McDonnell Douglas Corp.*, 727 F.2d 202, 208 (2d Cir. 1984) (recognizing the interplay of Rules 403 and 702); *Viterbo* v. *Dow Chemical Co.*, 826 F.2d 420, 422 (5th Cir. 1987) (noting that evidence admissible under Rule 703 must also satisfy Rule 403, which excludes evidence if its probative value is outweighed by other factors). Even the case upon which Petitioner relies for the "proper" construction of Rule 703—*DeLuca*—recognizes that the Rules are to be construed together. 911 F.2d at 952-57 (recognizing the interplay in admissibility decisions of Rules 403, 702 and 703).

inquiry into the foundation and reliability of the testimony. *Richardson*, 857 F.2d at 829; *Ealy*, 897 F.2d at 1161-62; *DeLuca*, 911 F.2d at 952, 958. In fact, the *DeLuca* Court remanded that case so that the lower court could conduct its own "record-supported, factual finding" as required by Rule 703 and the other applicable Rules of Evidence. *DeLuca*, 911 F.2d at 953.

The *DeLuca* Court furthermore expressly acknowledged that, following that case-specific inquiry, the Bendectin issue could be resolved on remand by summary judgment. 911 F.2d at 958. Accordingly, although *DeLuca* remains nonfinal at this point, the possibility remains that the Third Circuit could yet join the other circuits (the First, the Fifth, and the D.C. Circuits) in holding the available Bendectin evidence insufficient as a matter of law to prove causation. There is therefore no existing conflict on either the requirements of Rule 703 or the issue of causation in a Bendectin case meriting this Court's attention on certiorari.

CONCLUSION

For all the foregoing reasons, the petition should be denied.

Respectfully submitted,

WALTER A. SMITH, JR.*
STEPHEN G. VASKOV
WILLIAM P. FLANAGAN
HOGAN & HARTSON
Columbia Square
555 13th Street, N.W.
Washington, D.C. 20004-1109
(202) 637-5728
Attorneys for Respondent Merrell Dow Pharmaceuticals Inc.

March 5, 1991

* Counsel of Record